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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/155,590	09/30/98	SCHLOM J	2026-4230US1

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EXAMINER	
EWOLDT,G	
ART UNIT	**PAPER NUMBER**
1644	11

DATE MAILED: 05/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/155,590	Applicant(s) Schlom et al.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Mar 2, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-65* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-65* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply With Sequence Requirement

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald Ewoldt, Art Unit 1644, Group 1640, Technology Center 1600.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, the sequences of claims 10, 28, 29, and 38 must be brought into sequence compliance. Additionally, the claims should be amended to identify the sequences by SEQ ID NOs.

3. Restriction is required under 35 U.S.C. 121 and 372.

4. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

I. Claims 1-37, drawn to a mutant *ras* peptide and a pharmaceutical composition thereof, classified in Class 424, subclass 185.1.

II. Claim 38, drawn to a pharmaceutical composition comprising two or more mutant *ras* peptides, classified in Class 424, subclass 185.1.

III. Claims 39-41, drawn to an antigen presenting cell (APC) pulsed with a mutant *ras* peptide, classified in Class 435, subclass 343.2.

IV. Claims 42-44, drawn to a DNA, a plasmid, and a virus vector, classified in Class 536, subclasses 23.5, 69.1, and 455.

V. Claims 45-49, drawn to a method preventing or inhibiting tumor growth comprising *in vitro* generation of mutant ras specific CTL, classified in Class 424, subclass 93.71.

VI. Claims 50-53 and 60-62, drawn to a method preventing or inhibiting tumor or cancer growth comprising *in vivo* generation of mutant *ras* specific CTL, classified in Class 424, subclass 93.71.

VII. Claims 54-55, drawn to a method of eliciting a mutant *ras* specific CTL, classified in Class 424, subclass 93.71.

VIII. Claims 56-57 and 63-65, drawn to a mutant ras specific CTL, classified in Class 435, subclass 372.3.

IX. Claims 58-59, drawn to a method of eliciting a mutant ras specific CTL with a mutant-*ras*-loaded APC, classified in Class 424, subclass 93.71.

5. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under unity of invention practice as it applies to cases filed under 35 U.S.C. 371, unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

A) A product and a special process of manufacture of said product.

B) A product and a process of use of said product.

C) A product, a special process of manufacture of said product, and a process of use of said product.

D) A process and an apparatus specially designed to carry out said process.

E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and a method of making a product as claimed in the instant application, see MPEP § 1850.

6. Accordingly, Groups I-IX are not so linked as to form a single general inventive concept and restriction is proper.

7. Groups I-IV and VIII are different products. The peptides and pharmaceutical compositions of Groups I and II are chemically different structures than the DNA and vector of Group IV. The pharmaceutical compositions of Groups I and II are different in that the combinations of peptides of Group II will have different structures and have different modes of action than an individual peptide of Group I. He antigen presenting cells of Group III are of different lineage and have a different function than the T cells of Group VIII. Therefore, the different products are patentably distinct

8. Groups V-VII and IX are different methods of use. These inventions require different ingredients, process steps, and/or endpoints. Therefore, they are patentably distinct.

9. Groups (I-II) and Groups (V-VII) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in a materially different process such as immunopurification procedures or diagnostic or detection assays.

10. Groups IX and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case the mutant-*ras*-specific CTL of Group VIII can be elicited by conventional immunization methods and the process can be used to elicit different responses such as a T helper response.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

12. Irrespective of whichever Group Applicant should elect, Applicant is further required under 35 U.S.C. § 121 to:

1) Elect:

A) A **specific** mutant *ras* peptide, a **specific** carrier molecule (such as one listed in claim 26, if one is desired) a **specific** biological response modifier (if one is desired), **specific** adjuvant or liposome formulation (if one is desired), and a **specific** additional compound (such as one listed in claim 37, if one is desired) (if Group I is elected).

B) A **specific** combination of mutant *ras* peptides (if Group II is elected).

C) A **specific** mutant *ras* peptide and a **specific** APC (if Group III or IX is elected).

D) A **specific** DNA encoding a **specific** mutant *ras* peptide, and a **specific** vector (if Group IV is elected).

E) A **specific** mutant *ras* peptide or combination thereof, a **specific** cytokine for adoptive transfer (if one is desired), a **specific** biological response modifier (if one is desired), and a **specific** tumor cell type (such as one listed in claim 46) (if Group V is elected).

F) A **specific** mutant *ras* peptide, a **specific** adjuvant (if one is desired), a **specific** biological response modifier (if one is desired), and a **specific** tumor cell type or cancer type (such as one listed in claim 46 or 61) (if Group VI is elected).

G) A **specific** mutant *ras* peptide (if Group VII is elected).

H) A **specific** mutant *ras* peptide, a **specific** tumor cell type (such as one listed in claim 46), and a specific HLA (such as one listed in claim 63) (if Group VIII is elected).

2) List all Claims readable thereon including those subsequently added. Currently Claims 1, 38, 45, 50, 54, 58, and 60 are generic.

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. The different mutant *ras* peptides are independent and patentable over one another because they elicit different specific CTL as responders; different carriers elicit different types of T cell responses such as Th1 or Th2; different biological response molecules (including cytokines) have different chemical structures and function by different mechanisms; the different compounds and compositions listed in claims 34 and 37 have different structures and functions and elicit different types of responses; different APCs, such as macrophages and B cells, are different cell types that respond differently to different antigens or cytokines; different vectors have different functional domains and will be expressed in different cells or under different conditions; different tumor or cancer cells respond differently to different treatments and the associated diseases have different pathologies and outcomes; different HLAs bind different sets of peptides and will elicit responses in different T cells.

Therefore the species of Groups I-IX are independent and patentable over one another.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and every other Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Patent Examiner
Group 1640
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May 9, 2000

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